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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,296	09/13/2000	Patricia Anne Nuttall	2369-1-002	3816

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KLAUBER & JACKSON
411 HACKENSACK AVENUE
HACKENSACK, NJ 07601

EXAMINER
BUNNER, BRIDGET E

ART UNIT	PAPER NUMBER
1647	20

DATE MAILED: 09/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/555,296	NUTTALL ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-7, 10, and 18-44, drawn to a histamine or serotonin binding compound of Figure 1, nucleic acid molecule, vector, host cell, and method of treating or preventing inflammation or allergic reaction.

Group II, claim(s) 1-7, 10 and 18-44, drawn to a histamine or serotonin binding compound of Figure 2, nucleic acid molecule, vector, host cell, and method of treating or preventing inflammation or allergic reaction.

Group III, claim(s) 1-7, 10 and 18-44, drawn to a histamine or serotonin binding compound of Figure 3, nucleic acid molecule, vector, host cell, and method of treating or preventing inflammation or allergic reaction.

Group IV, claim(s) 1-7, 10 and 18-44, drawn to a histamine or serotonin binding compound of Figure 4, nucleic acid molecule, vector, host cell, and method of treating or preventing inflammation or allergic reaction.

Group V, claim(s) 8-9, drawn to a histamine or serotonin binding compound that comprises a cyclic peptide.

Group VI, claim(s) 50, drawn to a transgenic animal that has been transformed by a nucleic acid molecule.

Group VII, claim(s) 51 and 18-44, drawn to a protein consisting of the Ra-Res amino acid sequence given in Figure 5.

Group VIII, claim(s) 51 and 18-44, drawn to a protein consisting of the Av-HBP amino acid sequence given in Figure 6.

Group IX, claim(s) 51 and 18-44, drawn to the Ih/Bm-HBP amino acid sequence given in Figure 7.

Group X, claim(s) 51 and 18-44, drawn to the Ih/Bm-HBP2 amino acid sequence given in Figure 8.

Group XI, claim(s) 51 and 18-44, drawn to the Ih/Bm-HBP3 amino acid sequence given in Figure 9.

Group XII, claim(s) 51 and 18-44, drawn to the Ih/Bm-HBP4 amino acid sequence given in Figure 10.

Group XIII, claim(s) 51 and 18-44, drawn to the Ih/Bm-HBP5 amino acid sequence given in Figure 11.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the technical feature of a FS-HBP1 protein, nucleic acid molecule, expression vector, host cell, which is not required by the other products of Groups II-XIII.

Group II recites the technical feature of a FS-HBP2 protein, nucleic acid molecule, expression vector, host cell, which is not required by the other products of Groups I and III-XIII.

Group III recites the technical feature of a MS-HBP1 protein, nucleic acid molecule, expression vector, host cell, which is not required by the other products of Groups I-II, and IV-XIII.

Group IV recites the technical feature of a D.RET6 protein, nucleic acid molecule, expression vector, host cell, which is not required by the other products of Groups I-III and V-XIII.

Group V recites the technical feature of a cyclic peptide, which is not required by the other products of Groups I-IV and VI-XIII.

Group VI recites the technical feature of a transgenic animal, which is not required by the other products of Groups I-V and XIII.

Group VII recites the technical feature of a protein consisting of the Ra-Res amino acid sequence (SEQ ID NO: 5), which is not required by the other products of Groups I-VI and IX-XIII.

Group VIII recites the technical feature of a protein consisting of the Av-HBP amino acid sequence (SEQ ID NO: 6), which is not required by the other products of Groups I-VII and IX-XIII.

Group IX recites that technical feature of a protein consisting of the Ih/Bm-HBP amino acid sequence (SEQ ID NO: 7), which is not required by the other products of Groups I-VIII and X-XIII.

Group X recites that technical feature of a protein consisting of the Ih/Bm-HBP2 amino acid sequence (SEQ ID NO: 8), which is not required by the other products of Groups I-IX and XI-XIII.

Group XI recites the technical feature of a protein consisting of the Ih/Bm-HBP3 amino acid sequence (SEQ ID NO: 9), which is not required by the other products of Groups I-X and XII-XIII.

Group XII recites the technical feature of a protein consisting of the Ih/Bm-HBP4 amino acid sequence (SEQ ID NO: 10), which is not required by the other products of Groups I-XI and XIII.

Group XIII recites the technical feature of a protein consisting of the Ih/Bm-HBP5 amino acid sequence (SEQ ID NO: 11), which is not required by the other products of Groups I-XII.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a. a histamine or serotonin binding compound which has a binding site comprising amino acid residues phenylalanine, isoleucine or leucine at position at position I, tryptophan at position II, and aspartate or glutamate at positions III and IV.

b. a histamine or serotonin binding compound which has a binding site comprising amino acid residues phenylalanine or isoleucine at residue I, tryptophan at residue II, and aspartate or glutamate at residues III or IV.

c. a histamine or serotonin binding compound which has a first binding site comprising amino acid residues phenylalanine, isoleucine or leucine at position at position I, tryptophan at position II, and aspartate or glutamate at positions III and IV and the

second binding site comprising amino acid residues phenylalanine or isoleucine at residue I, tryptophan at residue II, and aspartate or glutamate at residues II and IV.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (a) is the histamine or serotonin binding compound which has a *single* binding site comprising amino acid residues phenylalanine, isoleucine or leucine at position at position I, tryptophan at position II, and aspartate or glutamate at positions III and IV. This special technical feature is not shared by any of the other species.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

d. a histamine or serotonin binding compound which comprises a peptide

e. a histamine or serotonin binding compound which comprises a synthetic compound

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (a) is the histamine or serotonin binding compound which is a peptide, composed of amino acids. This special technical feature is not shared by any of the other species.

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

f. a histamine or serotonin binding compound that is genetically fused to one or more peptides

g. a histamine or serotonin binding compound that is chemically fused to one or more peptides

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (a) is the histamine or serotonin binding compound which is genetically fused to a peptide. This special technical feature is not shared by any of the other species.

9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

h. a cysteinyl leukotriene

i. a platelet activating factor

j. a thromboxane

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (a) is a composition comprising a histamine or serotonin binding compound and a cysteinyl leukotriene. This special technical feature is not shared by any of the other species.

If Applicant selects Groups I-IV, one species from the (i) binding site group, (ii) the type of histamine/serotonin binding compound, (iii) the type of peptide fusion, (iv) and the type of additional peptide in a composition must also be chosen to be considered fully responsive.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

BEB
Art Unit 1647
September 27, 2002

Gary L. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600